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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/290,798	04/13/1999	INGEGERG HELLSTROM	9632-033	1277

7590 08/25/2004
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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/290,798

Applicant(s)

HELLSTROM ET AL.

Examiner

Christopher H Yaen

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2004.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 101-106, 109-116 and 120-127 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 101-106, 109-116 and 120-127 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Re: Hellstrom *et al*
Priority Date: 30 June 1989

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.
2. The amendment filed 3/1/2004 is acknowledged and entered into the record. Accordingly, claims 1-100,103,107-108, 117-119, and 128 are canceled without prejudice or disclaimer.
3. Claims 101-102,104-106,109-116,120-127 are pending and examined on the merits.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting Maintained

5. The rejection of claims 101-106,109, 112-116, and 120-127 under the judicially created doctrine of obvious type double patenting is maintained for the reasons of record. Applicant requests that the rejection be held in abeyance until allowable subject matter is found, at which time the applicant will file a terminal disclaimer.

Claim Rejections Maintained- 35 USC § 103

6. The rejection of claims 101-106,109-116, and 120-128 under 35 USC § 103(a) as being obvious over Abe *et al* (Cancer Res. 1986; 46:2639-2644) in view of Oldham *et al* (J Biol. Resp. Modif. 1983;2:1-37) and now in view of newly cited Sahagan *et al* (J.

Immunol. 1986; 137(3): 1066-1074) is maintained for the reasons of record. Applicant argues that an amendment to the claims to recite an immunoconjugate that comprises an antibody, wherein the antibody further comprises a human Fc region would render the claims non-obvious. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The claims are drawn to an immunoconjugate comprising an antibody joined to a therapeutic agent, wherein the antibody portion of the immunoconjugate is capable of competitively inhibit the binding of the deposited antibody BR96 and wherein the antibody further comprises a human Fc region.

The following paragraph is a summary of the examiner's statements made in the final office action mailed 12/31/2003. Abe *et al* taught an AH6 antibody that is able to bind an epitope that is identical to the one bound by BR96. Applicant argued that the BR96 antibody bound to an extended form or a variant form of Lewis Y antigen, and because the epitope bound by the AH6 antibody of Abe *et al* also binds to the same epitope, and because the office does not have the facilities to determine if the epitopes bound by the claimed antibody and that taught by Abe *et al* are in fact different, in the absence of factual evidence to the contrary, the antibody of the prior art reads on the instantly claimed antibody. Although Abe *et al* do not specifically characterize the antibody as being in the form of an immunoconjugate, one of skill in the art would have been motivated to couple the AH6 antibody to a therapeutic agent to form an immunoconjugate wherein the antigen binding domains target drugs or cytotoxic agents to carcinomas, because Abe *et al* taught the effectiveness and targeting ability of the

AH6 antibody for carcinoma. Further, it was well known in the art at the time the invention was made that the conjugation of drugs or cytotoxic moieties to an antibody was well established in view of Oldham *et al.*

Sahagan *et al* (J. Immunol. 1986; 137(3): 1066-1074) teach the construction of a chimeric antibody comprising a mouse variable region and a human constant region, wherein the purpose of such a construction is to reduce the side effects associated with mouse constant regions in eliciting unwanted immune responses (see page 1066).

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make an immunoconjugate that comprises an antibody that competitively inhibits the binding of BR96 that is joined to a therapeutic moiety and further comprises a human fc region. The motivation and expectation of success for making the immunoconjugate wherein the antibody that competitively inhibits the binding of BR96 is joined to a therapeutic moiety has been previously presented (see office action mailed 12/31/2003). One of skill in the art would have been further motivated to make an antibody that comprises a human fc region, because Sahagan *et al* taught that mouse antibodies that are effective at targeting antigens often produce undesired side effects i.e. immune response against the antibody (see page 1066), thus to circumvent this problem, the addition of a human fc region onto a mouse antibody would "produce an antibody that was capable of escaping surveillance by the human immune system" (see abstract) and retain target specificity. There would also be a reasonable expectation of success in doing so because Sagahan *et al* taught that such a chimeric antibody was capable of specifically recognizing its target and at the

same time reduce the chance of raising an immune responses against the chimeric antibody. Thus, the rejection of the claims under 35 USC 103(a) as being obvious is maintained for the reasons of record.

Conclusion

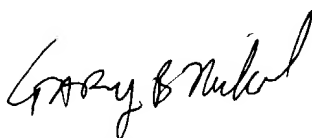
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
August 18, 2004


GARY NICKOL
PRIMARY EXAMINER